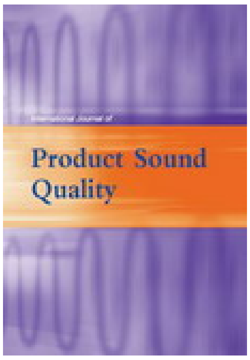

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Design, finite element analysis and fabrication of composite orthoses for bunions: a comprehensive study

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Abstract: This paper details the development and fabrication of an external support, designed to non-invasively correct mild to moderate cases of hallux valgus (HV), or bunions. Two external orthopedic models, constructed from composite materials, are developed. Each model consists of a polymeric shell wrapping around the foot and two toes, and a metal or carbon fibre insert that keeps the large toe straight and produces resistance. The models allow for the toes to stay spaced and parallel. The models were designed using SolidWorks© and their structural integrities were analysed with the included finite element analysis (FEA) package. The polymeric shell is made of a soft polymer and the inserts have been made of aluminium and steel. Displacement values and von Mises stress values obtained by FEA simulation were verified by the MATLAB© program written for this foot support. The first model was constructed using 3D printing techniques to validate the findings.

Keywords: bunions; composite; finite element analysis; FEA; simulation; 3D printing; orthoses.

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Biographical notes: Simin Nasseri obtained her PhD in Mechanical Engineering from Sydney University. She has been working at Kennesaw State University (KSU) since 2006. She has about 25 years of academic/industry experience. In addition to journal/conference papers and book chapters, she has published a book titled: “Solving Mechanical Engineering Problems with MATLAB”. Her research experiences are related to biomechanical engineering (artificial organs and soft tissue rheology), manufacturing, rheology and viscoelasticity, polymer processing, computational mechanics, robotics, and micromachinery. She has won many fellowships, awards and grants. In 2019, she received the KSU distinguished professor award, for excellence in teaching, research and service.

Mohammad Jonaidi obtained his PhD from Sydney University and is currently working at Kennesaw State University. During 38 years of research and industry professions, he has been involved in analysis and design of complex structural projects such as: FEA of high-rise buildings/steel structures, floor vibration for concrete slabs/pedestrian bridges, serviceability vibration analysis of high-rise buildings, earthquake engineering, post-tensioned concrete structures, nonlinear and buckling analysis of thin-walled cylinders, analysis of long span spatial steel structures, analysis of glazing façade, below grade shoring walls, retrofit of concrete structures using fibre reinforced polymers (FRP), and the strengthening of structures to resist progressive collapse.

Salim Kortobi is currently pursuing his BSc in Mechanical Engineering, with minors in Engineering Design Graphics and Manufacturing Engineering Technology at KSU. He is a Certified SolidWorks Expert in Mechanical Design (CSWE). He has extensive knowledge in 3D printing and has used that knowledge to assist in equipment procurement and the establishment of the BioMechanical Engineering Lab at KSU. As Dr. Nasseri’s research assistant, his work has included various research projects including the finger, foot and spine supports. He also has used his knowledge in Computer Aided Engineering (CAE) to run various SolidWorks simulations as part of the BME research.

George Williams obtained his BSc in Mechanical Engineering from KSU in 2021. He has worked with Dr. Nasseri’s BME team to develop non-invasive orthoses for treating musculoskeletal pathologies; and with Dr. Jonaidi to develop novel relief details for column-slab connections in reinforced concrete. As a former President of Kennesaw Motorsports, he designed and manufactured performance IC/EV powertrain components for Formula SAE vehicles. He currently works as a Mechanical Engineer at Compass Technology Group, LLC, focusing on electromechanical design/drafting, conventional/computational analysis in structural, fluid/thermal/EM systems (FEA, CFD, CEM), manual and CNC machining, computer-aided manufacturing (CAM), and industrial control systems integration.

Logan Willis graduated from Kennesaw State University in 2020 with a Bachelor’s degree in Mechanical Engineering. During his time at KSU, he joined Dr. Nasseri’s team as a research assistant to help create custom orthotic devices for foot and spine support. Shortly after graduating, he obtained a full-time position as an engineer and worked on predictive maintenance systems for water transportation systems.

1 Introduction

Foot deformities affect individuals' ability to walk and perform everyday tasks. The most common of these deformities, globally, is hallux valgus (HV), or bunions. HV is a foot deformity presenting as an abduction of the hallux, or large toe, resulting in increased pressure on other joints and ligaments in the foot. Women and the elderly show an increased incidence of HV. Most people who suffer from HV have trouble walking, as it causes discomfort or pain during movement. HV is defined as an abnormal angulation of the great toe, or hallux, which deviates laterally; and the first metatarsal, or second toe, which deviates medially (Tamer and Simpson, 2017). These deviations are caused by tensile forces generated in the long flexor and the extensor tendon in the foot, resulting in the medial rotation of the metatarsal head. This motion causes encroachment of the great toe upon the second and third toes. The abnormality applies pressure on the other toes and the side of the foot, causing discomfort or pain while the individual is in motion. HV is often associated with poor balance, foot pain, and overall decreased quality of life. In a 2017 study, Tamer and Simpson concluded that evolution is a major cause of bunions in humans. Their research on the walking movements of humans compared to other primates identified that the walking pattern of humans places an oblique shear stress and axial torsion on the Flexor hallucis longus and Flexor hallucis brevis. The oblique shear stress and axial torsion from walking results in the displacement of the hallucial sesamoids and the intervening Flexor hallucis longus tendon, contributing to the formation of bunions.

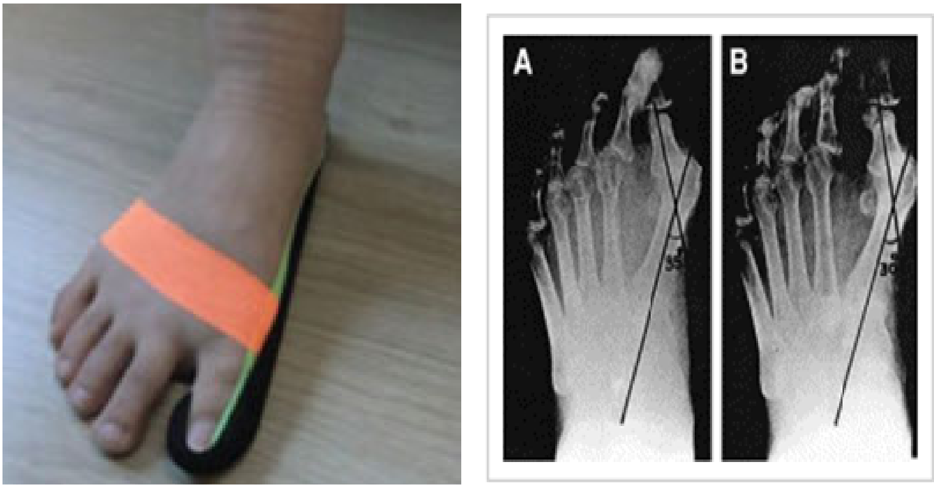
Risk factors for developing HV include familial history, physiological deficiencies, and environmental factors. Functional tightness of the Achilles tendon, the structure of the pes planus, and even degenerative joint disease at the first metatarsophalangeal (MTP) joint, are recognised physiological risks for HV. There is also a key environmental factor: people who wear ill-fitting shoes, such as those with pointed toe boxes or high heels, are distinctly more susceptible to HV. When compared to individuals who wear shoes with ample toe room and decent arch support, an increased incidence of the incident of HV by up to 15 times has been observed. As women tend to wear pointed shoes, like high heels, more than men, a female-biased distribution results when comparing the relative incidence of HV (Tamer and Simpson, 2017).

Dunn et al. (2004) conducted research on the most common foot deformities in a multiethnic sample of individuals. Their study found that, among a random test group of 784 individuals aged 65 and older, bunions were the third most common foot deformity found at 37.1%. The study also found that, throughout the sample, 44.3% of women had bunions and 25.3% of men had developed the deformation. Their report continues to examine the sample for other pre-existing health conditions that may affect their overall health in relation to the foot deformities (Dunn et al., 2004).

The treatment options for HV fall into two categories: surgical and non-surgical (Holmes and Hsu, 2014). The current surgical method of fully correcting HV is a costly and invasive surgery, with an extensive recovery period. The average cost for surgery as of 2014 was $18,332 and had a range from $3,542 to $52,207 (Wiley et al., 2014). This cost is out of reach for many individuals. Due to these factors, more conservative and non-surgical methods have been developed and are still being researched.

Applying non-invasive HV correction methods, physical therapists Lee and (2016) applied kinesiology tape to a patient experiencing pain from HV [shown in Figure 1(a)]. The patient said she was having pain over the hallux MTP joint when walking. The physical therapists applied the tape to both of the patient's large toes and studied the effect of wearing it for about 16 hours a day over a 3-month period. The conclusion was that the patient's HV angles significantly decreased, and she was then able to walk long distances wearing shoes without pain in the MTP. The study suggests that using kinesiology tape for complementary treatment of moderate HV significantly decreases the severity of the deformity (Lee and Lee, 2016). Figure 1(b) shows HV with severe subluxation of the first MTP joint. The HV angle is 35 degrees. It improved to 30 degrees after a total contact insole with a fixed toe separator was worn (Tang et al., 2002).

Figure 1 (a) Patient with kinesiology tape applied to foot to help correct hallux valgus deformity (Lee and Lee, 2016) (b) Improvement of hallux valgus deformity after the total contact insole with fixed toe separator was worn (see online version for colours)



(a) (b)

Source: Tang et al. (2002)

Martijn and colleagues (2018) conducted a systematic review of multiple bunion correction procedures by measuring the intermetatarsal angle (IMA), metatarsophalangeal angle (MPA), and the American orthopedic foot and ankle society Lesser Metatarsophalangeal-Interphalangeal scale and satisfaction scores. They concluded that the distal osteotomy represents the best compromise in reducing the IMA, MPA, and the greatest rate of satisfaction (Martijn et al., 2018).

A trial was conducted by Torkki et al. (2001) in which the orthoses were custom-made by a certain casting technique. Specific prescriptions were also given based on the case-by-case deformation of the foot. The cast and prescription were sent to a lab where the polypropylene orthoses were fabricated. At year two of the study, patients that used the orthoses responded with the same level of satisfaction as the surgically treated patients. (Torkki et al. 2001).

Lui (2017) studied the underlying reason for recurrence of HV after bunion surgery. Their study found that many factors contribute to the recurrence of a bunion: patient related factors, surgery related factors, and the initial state of the bunion. The most common way to correct a recurrent bunion requires correction of the bone alignment, restoration of joint congruity, and achieving soft tissue balance (Lui, 2017).

People with general hypermobility, ligamentous laxity, or neuromuscular disorders also have a high recurrence rate. Some non-operative options are night splints, footwear modifications, shoe insoles, and physical therapy (Fraissler et al., 2016). More conservative non-surgical approaches are proper fitting footwear that have a wide and deep toe box, non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, and muscle relaxants (Chadchavalpanichaya et al., 2017). Within the toe separator category of bunion correctors, there are cheaper prefabricated silicon toe separators (TS) on the market, but these boast lower effectiveness when compared to surgery. The prefabricated silicon TS also have a lower compliance rate because they are not customised to the individual. Consequently, they often do not fit the patients' feet very well, leading to some discomfort, which leads to patients being less likely to wear them. Custom-moulded TS have been researched and show good patient outcomes (Chadchavalpanichaya, 2017).

There also exist some unconventional methods that have been used in attempt to correct HV. A study was conducted by Brantingham et al. (2005) in this field using chiropractic methods, specifically graded mobilisation and localised cryotherapy. Furthermore, in this work, patients received a progressive mobilisation of the first MTP joint and cryotherapy to the foot (Brantingham et al., 2005). The progressive mobilisation is a technique used often in chiropractic therapy where joints are manipulated in specific directions and at different speeds to eventually regain movement. It was determined by Hurn et al. (2016) that more than 50% of the 1,900 Australian podiatrists that were surveyed recommended non-surgical treatment. This sort of physiotherapy is one of the non-invasive treatments that were commonly suggested (Hurn et al. 2016).

Cryotherapy is also another commonly used therapy technique that exposes the body to very cold temperatures, in this case to reduce pain caused by the bunion. Brantingham et al. (2005) concluded that this chiropractic technique was effective in helping alleviate pain caused by HV, but not a method that should be used in overall deformity correction (Brantingham et al., 2005). Another unconventional approach to treating HV was used at The London Bunion Clinic. There, electrotherapy was used to apply microcurrent attempting to regenerate some tissue in the foot and eventually use physiotherapy to complement the correction of the bunion (Ng, 2016).

Zhang et al. (2018) constructed FE models of a normal foot as well as a foot with severe HV and analysed them using stress distribution, contact pressure and force. The feet with HV exhibited higher stress at the MTP joints, which indicated that patients with HV do have a greater risk of injury and functional impairment (Zhang et al., 2018).

Wong et al. (2020) created a computational foot model to analyse how generalised ligament laxity affected the risk of HV. It was determined through FEA analysis that generalised ligament laxity did affect the load-bearing ability of the first metatarsal which could lead to HV and other foot problems (Wong et al., 2020).

Yu et al. (2020) hypothesised that shoe wearing played an important role in the development of HV. A model of the bear-footed Homo Naledi was created from a fossil and compared to modern day wrestlers who wore shoes. It was determined that the MTPJ angle increased in every athlete studied with the exception of one, however, further study was recommended (Yu et al., 2020).

Cao et al. (2023) used simulations to study the effects of minimally treating HV and it was determined that when the first metatarsal was shifted surgically by 4 mm that HV could be improved or cured (Cao et al., 2023).

In 2016, Australian podiatrists conducted a study for patients who presented their bunions to doctors. The patients expressed their desire to use non-surgical management for treatment of the HV. (Hurn et al. 2016).

Glasoe et. al. (2010) concluded that HV is affected by the collapsing of the foot arch as a person ages. The collapsing arch causes the big toe to shift medially. This ultimately leads to an individual developing bunions, and a decrease in quality of life. The authors propose that by using an orthotic (shoe insert) to support the arch of the foot will lessen the chances of the deformity occurring. The orthosis is designed to support the foot's arch and prevent the big toe from altering the alignment of the foot (Glasoe et al., 2010). Glasoe and others developed a foot-toe orthosis and tested on seventeen patients with HV who agreed to participate in the outpatient study. The patients wore the insoles for 3 months. They concluded that the insole reduced the patients' pain and improved their walking ability drastically. Following the study, the angle of the HV was also not as severe, as shown in Figure 1(b). It was referred to as 'an effective alternative treatment for patients.' (Glasoe et al., 2010). Therefore, in this paper some special insoles, and an adhesive bandage are designed to treat the bunion.

In this research, a new composite support is designed to correct bunions gradually, which addresses most of the issues in the previous supports available in the market. A finger support was previously designed, fabricated and tested which used the same principles (Nasseri et al., 2018a, 2018b). A large factor for choosing a brace over the corrective surgery is that it allows the patient to go about their daily activities, while wearing the brace, with full mobility. The design and materials chosen for the patent pending brace in current research were selected with patient mobility as a priority. The polymer that surrounds the toes allows for a comfortable fit that can be worn for extended periods of time. The support corrects the deformity by applying a slight pressure in the opposite direction of the curvature. This results in the gradual straightening of the joint. The use of the metal insert allows the soft polymer to be used for comfort while the metal provides the rigidity needed to correct the deformity. The polymer surrounding the toe is connected to both the other toe and a strap that surrounds the foot and prevents the support from twisting while it is worn. The combination of these design features allows for effective correction of the deformity, with patient use and comfort as a priority. The models chosen for analysis and fabrication allow the patient to wear the support at any stage of the HV development, allowing the correction process to begin. In both models, the insert can be bent and straighten over time to provide a gradual corrective force on the large toe.

2 Materials and methods

For this study, a model was constructed that has the minimal effect on the user's everyday life, but still provides correction for the patient. The model developed has very thin wraps for the foot and toes to allow the support to be worn within a shoe, allowing for daily use. The wrap around the foot provides a location for a reaction force. This reaction helps to correct the deformity by pulling the toes in the opposite direction of the deformity. The thin wraps around the toes allow for the correction of both the largest toe and the toe beside it. The area that is wrapped around the toes also has a spacer that separates the two toes. The support is constructed of a polymer-based material with a solid support insert used to correct the deformity. The solid support insert was simulated as two different materials, and results were gathered. The support was first constructed using a 3D printable polymer, known as TangoPlus. This material is satisfactory for a prototype, but not for any practical use of the support. The suitable polymer might be a thermoplastic elastomer such as thermoplastic polyurethane (TPU) or Ninjaflex®. They have superior properties for this application such as elasticity, transparency, and resistance to oil, grease, and abrasion. The design allows for maximum mobility and correction for the patient (Figure 2).

Figure 2 Composite foot support comprised of flexible polymer (3D printed) and inserted support metal. the support is designed to provide maximum correction with the least amount of interference with everyday life (see online version for colours)

The force of the toe deformity is applied to the insert or beam that is inserted into the support. The beam acts as a cantilever, and correct equilibrium equations can be applied to the beam so that forces can be found and simulated. In a study conducted by Frassiler et al. (2016) on the treatment of HV, it was found that the deformity, depending on the severity, can have an angle ranging from 15 to 45 degrees. From this information and the research conducted for the development for a finger support, an inward rectangular distributed load equal to 2 Newtons on the toes was applied and an outward triangular distributed of 1 Newton was applied to the beam where the side of the foot or bunion is in contact with the support.

For the healthy foot case, when the effect of the bunion force is minimal, the toe is exerting a force on one point (for example at the tip of the support), and the deflection of the beam is given by equation (1).

$$\Delta = \frac{FL^3}{3EI} \tag{1}$$

where Δ is the deflection of the beam at the tip, F is the force exerted by the toe (here tip of the beam), L is the length of the beam, E is the elastic modulus of the material (For example in GPa), and I is the area moment of inertia (for example in mm^4). Total length L here is 114.3 mm (excluding the length of the strap around the foot) and the length of the top part, where the large toe is inserted, is one inch (25.4 mm).

The deformity causes the toes to put a force (towards other toes) on the inserted beam, and the bunion applies the force outward on the cantilever beam. For the various materials tested the modulus of elasticity (E) is required and is a material property. To derive the displacement and slope of a beam the ‘conjugate beam method’ is used. Therefore, the following equations can be used to validate the FEA and results:

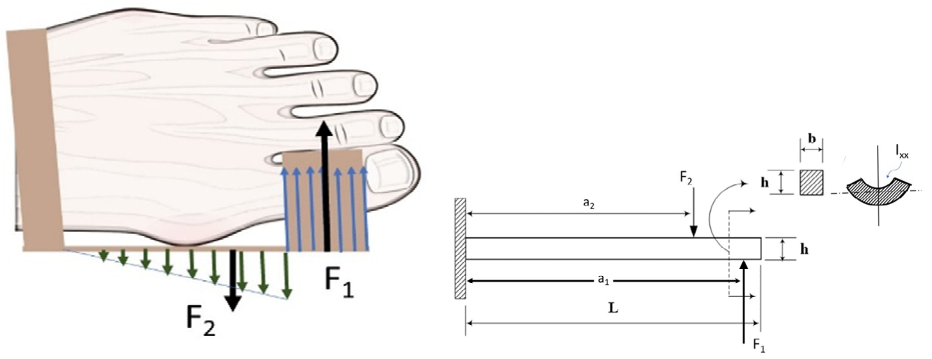
$$\sigma = \frac{6M}{bh^2} \tag{2}$$

$$\sigma = \frac{My}{I} \tag{3}$$

$$\Delta = \sum_{i=1}^{2} \frac{F_i a_i^2}{2EI}\left(L - \frac{a_i}{3}\right) \tag{4}$$

M is the moment produced by each force, σ is the stress (equation (2) for a rectangular cross section and equation (3) for a curved cross section shown in Figure 3) and a is the location of each force on the beam relative to the fixed end. Equation (4) is used for the maximum deflection of the beam when more than one force are applied (F_i) and their locations are specified (a_i).

Figure 3 Force arrangement for the foot with a bunion (see online version for colours)



(a) (b)

Notes: The conjugate beam method is used to find the stress and displacement of the tip of the inserted sheet. $F_1 = 2$ N and $F_2 = 1$ N. The curved cross section for the inserted sheet of metal is considered in both MATLAB© and Solidworks© Modelling

To predict the maximum deflection and maximum stress, a MATLAB© (MathWorks) program was written for a beam under two-point loads (Figure 4). These loads are the equivalent loads of the two distributed loads shown in Figure 3. One force is rectangular for the toe and the other is triangular for the bunion. The user enters the inputs (parameters mentioned above and written in Table 1) and receives the output values which are the max displacement and the max normal stress values. This program was useful to predict the deflection and stress values and therefore to validate the results which were obtained by simulation. Besides, the program compared the max normal stress to the yield or tensile strength of the material to obtain the factor of safety to estimate how much the forces can be increased.

Table 1 MATLAB© program assigned dimensions for the inserted sheet in the composite foot support with a curved cross section

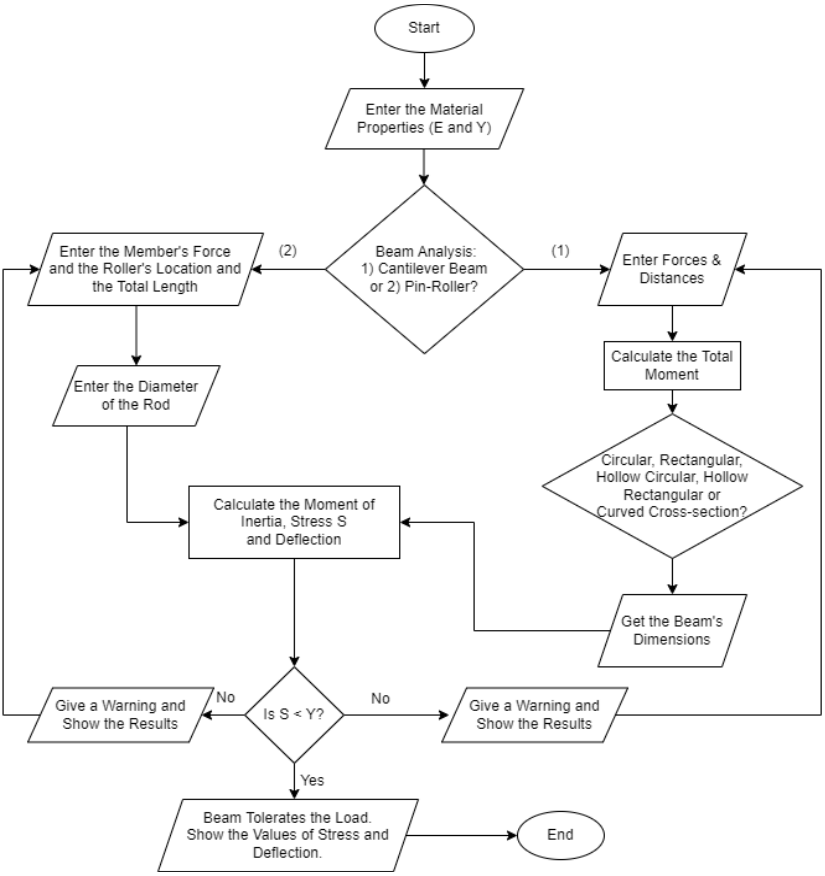
Total length, L	*Distance of force F_1 to fixed end, a_1*	*Distance of force F_2 to fixed end, a_2*	*Area moment of inertia, I*	*Distance from neutral axis, y*
114.3 mm	101.6 mm	59.267 mm	0.584 mm^4	0.779 mm

Note: These dimensions are used for the show sizes 6.5–7 for women as a case study.

The inserted metal can have a variety of cross sections which were tested in the MATLAB© program. These are circular, rectangular beam, hollow-circular, and hollow-rectangular. For the sake of simulation, all these shapes can be considered and the hollow-circular one results in the lowest area moment of inertia and the highest stress. Whereas considering the manufacturing limitations and the minimum thickness required, a rectangular beam has beam considered which allows the minimum thickness.

The algorithm for the MATLAB© program is as follows:

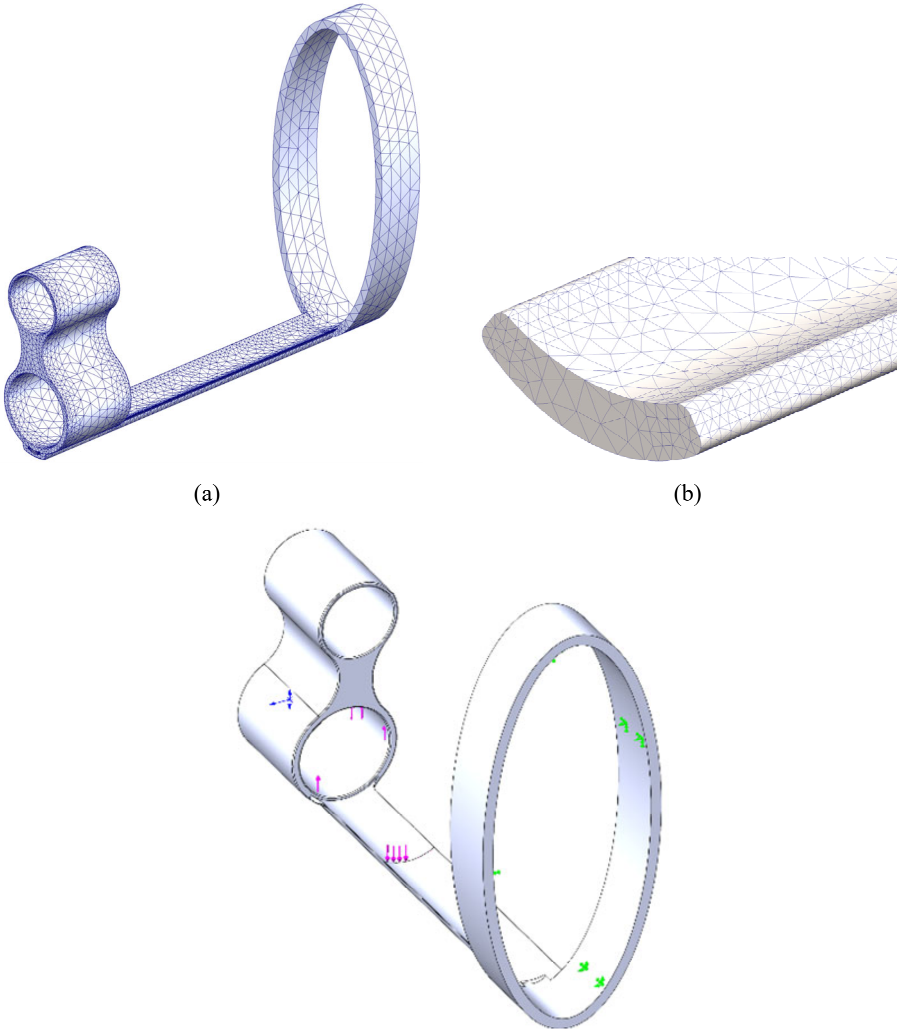
Figure 4 The flowchart of the MATLAB program which has been used for orthoses designed



Notes: the pin-roller condition is used for other biomedical support designed by the authors.

Various materials were considered when developing the beam. These were steel, aluminium and carbon fibre. Carbon fibre is light and has the highest strength. The beam dimensions are very small to allow the patient to wear the support inside footwear of their choice. These material properties are used in the FEA study to identify stresses, strains and displacements of the support with predicted loads applied.

Figure 5 (a) The h-adaptive curvature-based mesh using solid elements for static simulation to automatically refine the mesh and obtain convergence (b) The h-adaptive mesh of the inserted rod (c) The loading arrangement with two distributed loads (converted to point loads) applied as shown (right) (see online version for colours)



(a)

(b)

(c)

3 FEA simulation

The simulation was conducted in the SolidWorks© included FEA package (Kurowski, 2016). The software allows the model to be placed into a static loading condition for its results to be measured. The software tested the model made from a polymer (Nylon) with low modulus of elasticity E = 1,000 Mpa (Solidworks© package), and with support beams made of alloy steel and aluminium. The model was constructed with all sharp edges filleted where possible to reduce stress concentrations and prevent deflection or eventual failure. The model was also constructed with a minimum thickness of 1mm to aid in the fabrication process.

Finite element analysis (FEA) requires meshing such that the geometry can be mathematically analysed for stress, strain and deflection. The mesh type used is an ‘H-adaptive mesh’ (Figure 5). The H-adaptive method runs multiple studies and automatically locally and globally refines the mesh, based on the results of the previous iterations. The use of this mesh style allowed for quicker convergence and more accurate results. In this study solid elements were selected and element values were chosen for reading the stress values.

The static test performed on the model used a force of 2 N applied to the middle of the toe separator, and a 1 N distributed load applied to the side of the beam (2/3 of the length from the fixed support). This study was performed assuming that the shell was made with Nylon, and a beam made with two different materials as seen in Table 2.

Table 2 FEA material for foot support and beam

Study number	*Support beam material*	*Foot support material*
1	6061 T6 Aluminium alloy	Nylon
2	Alloy steel	Nylon

4 Fabrication using 3D printing

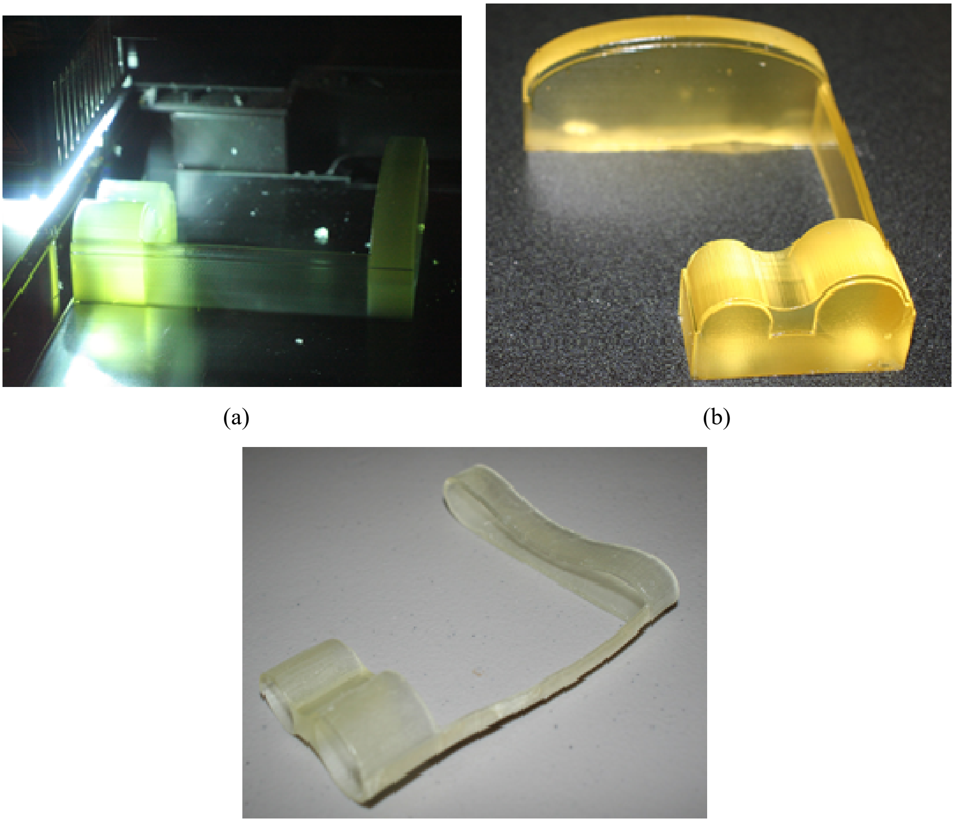
The fabrication method chosen for this model was a 3D PolyJet printer. The material used in the printer is TangoPlus Fullcure 930 with use of Fullcure 705 as the resin material. The use of the PolyJet printer allows for a fully supported print, necessary for a flexible model as seen in Figure 6(a). As experienced before for the finger support, the model with support material attached was placed into a pressure washing chamber, and the support material was carefully removed with water. Figure 6(b) shows the model before support material removal. It was then rinsed with low pressure water and prepared for the carbon fibre support insertion. Figure 6(c) shows the foot support after all support material is removed.

5 New features and other orthoses

To address the need for flexibility, comfort and similar factors, other useful models are designed and will be fabricated and simulated in near future. These are the adjustable bunion support, a composite bandage, and a shoe insole. Figure 7 and Figure 8 show these promising models which can alleviate the patient’s pain and slow the progress of the bunion deformity. The strap around the foot in Figure 7 is equipped with a raised pattern and slots to accommodate various sizes. All the edges should be smooth, so bevels are predicted in the model. This bunion support, like the previous one, is ideal to be used when the patient is at rest. For example, the patient can wear it at night for immediate relief. It will effectively ease pain and pressure on patients' feet. The support can also be placed inside slippers or wide shoes.

In an advanced resizable model [Figure 7(a)], the support is also equipped with hinges to allow the user to have more flexibility. The hinge will be at the location of large toe's Metatarsal-Phalangeal joint, allowing for rotation of ball of the foot with respect to the toes.

Figure 6 (a) The foot support being printed by the Polyjet printer with full support material (b) The foot support after removal from the Polyjet printer (c) Prepared for support material removal (middle) (see online version for colours)



(a) (b)

(c)

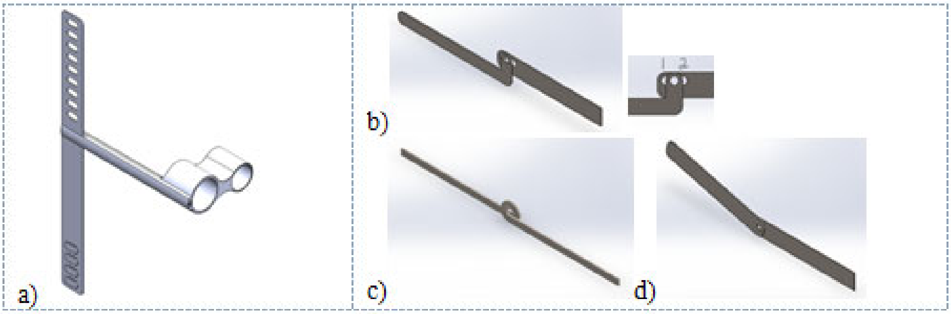
Notes: the foot support with all support material removed, ready for insertion of the metal or carbon fibre sheet.

- The support's metallic side-bar or metal insert is able to get compressed or stretched. This is achieved by the telescopic insert [Figure 7(b)] which allows extension or compression with a special lock. The total length of the slot can be controlled which affects the total length between the bunion towards the back strap. Since the strap for the foot is adjustable, this new feature will make the whole support versatile for a range of shoe sizes.

- The support is able to provide the rotation of the ball of the foot with respect to the heel. The motion is provide via dual bar-slot mechanism [Figure 7(b)], a simple loop [Figure 7(c)], or a simple pin [Figure 7(d)].

In Figure 7(b), in case it is needed to keep the metal insert straight, a pin can be inserted in area 1 [shown next to Figure 7(b)] to prevent the rotation of two part with respect to each other. To allow the rotation, a pin can be inserted in area 2, to push the L-shape part to the left. This mechanism acts as a lock for rotation/no rotation options [Figure 7(b)]. However, for simplicity, the rotation can be allowed and the slot length can be considered equal to the diameter of the pin plus the tolerance needed.

Figure 7 The adjustable bunion support (a) the insert is equipped with a hinge to allow the rotation of ball of the foot with respect to the toes (b, c and d) (see online version for colours)

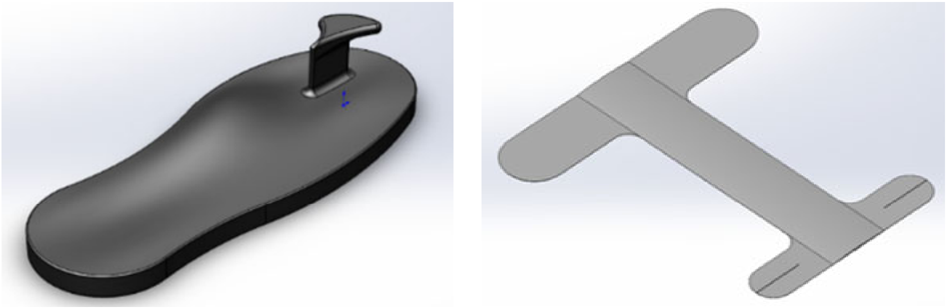


The proposed insole [Figure 8(a)] is not available in the market like other supports in this paper and is a solution to prevent further deformation of the large toe and the adjacent toe. In some cases, bunions are often associated with flat feet; placing insoles into shoes that are otherwise flat can help prevent bunions from worsening. The included model is ergonomic, providing suitable longitudinal and transverse arches for the foot and can be tailor-made to each patient depending on their needs. These inserts would provide separation of main toes paired with cushioning that better align the toes, preventing increased bunion severity. The toe-separator can have various shapes depending on the shoes worn. The height of the whole raised part (between the toes) is shorter at the front, as the insole should be fitted inside the shoe. The new model is predicted to have the following benefits:

- The raised part between the toes, is equipped with a flat wide top piece, which pushes the second toe downward. This is because the second toe is usually deformed (hammer toe) as a result of the deformation in the big toe. This part is considered to further reduce or prevent the deformations of the toes.
- The flat top piece is pointing towards the back of the insole. This part can point towards the front of the insole, depending on the patient's deformations in the toes.
- Because of the contoured base, the pressure that the body weight produces will be evenly distributed.

- The suitable arcs in the base prevent too much pressure from landing on the ball of the foot, therefore the forefoot will be relieved.
- The insole helps to reduce fatigue and discomfort to the feet, hips, legs, and knees.
- The insole improves balance reactions, increases blood circulation, and reduces muscle strain.

Figure 8 (a) The composite arched shoe insole for bunions equipped with the part to prevent the progression of the hammer toe the toe separator has a metal or carbon fibre insert (b) the profile of the proposed composite bandage for bunions (see online version for colours)



(a) (b)

Furthermore, the composite bandage [Figure 8(b)] follows the same principal of a shell with an insert. Here, a thin layer of carbon fibre is inserted in the bandage, providing a rigid support that can be used when needed, and later disposed. The insole can mainly be used in wide shoes, unless its dimensions are minimised which in turn are restricted by the capability of the manufacturing process used. For example, for 3D printing manufacturing process, there might be a minimum thickness that should be maintained.

6 Results

Various composite models were created, and extensive research was conducted to construct a flexible foot support to help patients with a HV foot deformity, more commonly known as a bunion. The support is designed to be flexible enough to be worn daily and provide gradual, non-surgical correction. This design features a flexible member that is placed onto the foot and toes with a rigid shaft that provides the needed stiffness to correct the joint deformity.

The material chosen to create the prototype was a soft flexible polymer known as TangoPlus Fullcure 930. This material was selected for the material properties that allow it to be worn by the patient with minimal irritation. However, upon removal of the support material, the model began tearing and became fragile and unsuitable for testing. Therefore, other more robust polymers such as TPU as mentioned before and DuraForm® Flex should be explored.

The von Mises theory compares properties of the material use, using a relationship between internal energy derived from stress and the tensile yield strength of the material.

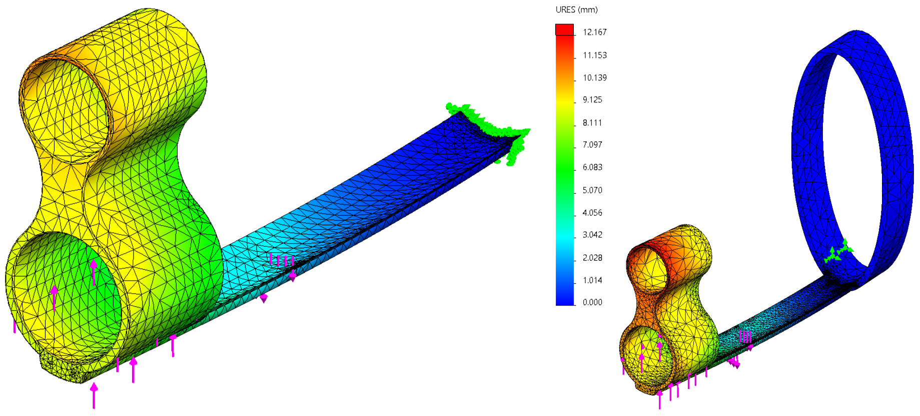
Throughout the simulations the maximum stress on the foot support was far lower than the yield strength of the tested materials.

Using the H-Adaptive mesh with a maximum mesh size of 0.020’ and a minimum mesh size of 0.005’, a total of 5 loops yielded a converged result that provided accurate stress data. This mesh study was applied to the flexible foot support with multiple rigid inserts including aluminium, carbon fibre and tool steel. The results can be seen below in Table 3: FEA foot support material analysis. Figure 9 show the modelling results for Aluminium. Steel insert allows the smaller displacement, whereas the stress values are comparable which shows that the SolidWorks© model was accurate.

Table 3 FEA Metal-polymer composite foot support material analysis

Beam material	*Elastic modulus (GPa)*	*Max. displacement (mm)*	*Max. stress (MPa)*	*Yield strength of material (MPa)*
Alloy steel	210	4.812	172.433	415
Aluminium 6061-T6 Alloy	69	9.971	169.344	276

Figure 9 (a) The displacement profile highlighting the areas with deflections for 6061 aluminium alloy metal insert in polymer support (b) The whole composite support is shown on the right (see online version for colours)



(a) (b)

Table 4 Comparisons between the results obtained by SolidWorks© (SW) and MATLAB© for max displacement δ (mm)

Beam material	*SW composite support*	*SW insert only*	*MATLAB©*
Steel	5.440 for Polymer, 4.812 for metal	5.410	5.419
Aluminium	12.167 for Polymer, 9.971 for metal	16.450	16.494

Tables 4 and 5 summarise the results obtained by the MATLAB© program in comparison with the SolidWorks© results for max stress (σ) and max displacement (σ). The distributed loading of 2 N has a distance of 101.6 mm to the fixed base, and the distributed loading of 1 N (in opposite direction) has a distance of 59.267 mm to the fixed base. MATLAB© program results are for the beam or inserted sheet of metal, whereas the SolidWorks© results reported are for the composite polymer-metal support as well as the inserted sheet of metal. In all analyses, the sheet of metal has a curved cross section.

Table 5 Comparisons between the results obtained by SolidWorks© (SW) and MATLAB© for max stress σ (MPa)

Beam material	*SW composite normal*	*SW insert only Von-Mises*	*SW insert only normal stress*	*MATLAB© normal*
Steel	172.433	166.799	180.514	192.324
Aluminium	169.344	166.392	185.283	192.324

Note: Element values are considered instead of node values.

7 Conclusions and discussion

Bunions are one of the most common foot issues faced by people around the world. The use of corrective surgery is the only current method of correction used by practicing medical doctors. Research on the construction and benefits of a flexible foot support is not very prominent in today's medical field. Thus, the research and information gathered in this study could provide grounds for furthering and diversifying the correctional methods that are currently available to patients. Research related to design and fabrication of foot supports for people with bunions is limited. This research will aid in the development of various foot supports which are perfected enough to be brought to the market. The purpose of this research was to design a composite foot support that is durable and comfortable and can be worn continuously to aid in the treatment of deformities especially for the large toe. This was achieved by considering a polymeric shell and a metal insert. The sheet of metal was considered to be aluminium 6061-T6 or alloy steel. Carbon fibre can also be explored in future studies because it is strong and light, however, due to fabrication limitations, this material could not be processed. The different polymeric shells investigated were TangoPlus in fabrication, and nylon in simulation. The simulation process was performed, and stress and displacement values were obtained.

For the results obtained by MATLAB© and SolidWorks©, the following factors can be considered:

- In all analyses, the sheet of metal has a curved cross section.
- In the MATLAB© program, only a sheet of metal is analysed, whereas SolidWorks© results are based on the whole polymer-metal composite support as well as the sheet of metal.
- The normal stress values obtained from SolidWorks© and MATLAB© are close for the case of the sheet of metal.
- The stress values for the composite support obtained from SolidWorks© are less than the ones obtained from MATLAB©, which is expected due to fact that MATLAB© only considers the sheet of metal.
- The displacement values obtained from SolidWorks© and MATLAB© are very close for the case of the sheet of metal. However, the displacement values for the composite models are smaller. This is due to the fact that the SolidWorks© model is

a composite of two materials (polymer and metal) and this has an effect on displacement, although the polymer has a much smaller elastic modulus.

- The polymer is stretched more on the top cylinder for the second toe, which shows that the polymer is stretched. This is because the large toe and the adjacent one (which would restrict the motion of the polymeric cylinders) are not considered in the simulation.
- In our FEA analysis, the curvature based solid elements were used. The whole length of the inserted sheet of metal is about 100 times larger than its thickness. It is advised that thin-walled parts should be meshed using solid elements to use at least three elements through the thickness. However it was noticed that the number of elements increased which resulted in higher CPU time and sometimes the failure in running the iterations.
- If increasing the number of solid elements is not possible, it is suggested to use the shell elements (first-order elements). However, shell elements might dangerously underestimate stress in key features [Langnau]. It is advised that using higher-order solid elements together with a curvature based meshing algorithm, would achieve highly accurate results [Langnau].
- There are many other factors that ought to be evaluated while simulating the composite parts, to prevent the spurious results. In this work many of these were explored such as the effect of standard elements versus H-adaptive elements (for stress accumulation in corners), solid elements and shell elements, stress values based on element values and node values, etc.

Most of the research projects related to bunions focus on evaluating the forces that the foot applies to the base and the stress distribution. The available foot supports are made of rough materials, and they are not accommodating different stages of the bunion's progress. For this research, 3D printing was selected to fabricate the foot support because this process is faster and less expensive compared to other manufacturing processes. In the fabrication of the foot support, TangoPlus was used which showed that it would not be a suitable material as it is not tear resistant enough. Better materials can be explored, such as TangoGray, TangoBlack, TPU, Agilus 30 FLX, or NinjaTek® products (such as NinjaFlex), etc. Several models were designed to address the deformity of the large toe and the adjacent toe. The flexible bunion support, as well as the insole and the composite bandage are proposed. After fabrication and thorough analysis using computer simulation, it was concluded that the designed foot support would alleviate pain and prevent further deformity by keeping the large toe straight and separated from the adjacent toe and reducing the angle of HV (also reported by many researchers such as Tang et al., 2002). Although the clinical assessment may not be needed, it would be good to conduct some laboratory mechanical testing to validate the results obtained by simulation. In this work, the MATLAB© program was used to validate the results obtained by simulation. In addition to the proposed fixed end condition for the beam for this foot support, the pin-roller condition will be examined in the future. A new spine support will also be designed and examined with various loading conditions.

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